K102298
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510(k) SUMMARY

TransTend Anchors

JAN - 7 2011

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767

Contact Person

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Prepared 10/30/2010

Name of Medical Device

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Common/Usual Name: Bone Anchor

Proprietary Name: TransTend Anchors

Substantial Equivalence

The proposed **TransTend Anchors** are substantially equivalent to:

- K100012 Gryphon Br – Hip (March 10, 2010)
- K090124 Gryphon P BR Anchor (March 11, 2009)
- K073412 Gryphon BR / Healix BR Anchors (January 17, 2008)
- K082282 Healix Ti Anchor (November 7, 2008)
- K071481 Healix Peek Anchor (August 9, 2007)
- K082810 Arthrex BioComposite Corkscrew Anchor (January 23, 2009)
- K081598 KFX Suture lock Nail Bone Anchor (July 3, 2008)
- K020159 Twin Fix Ti Quick T 3.5 mm Fixation System (March 26, 2010)

Device Classification

These devices carry an FDA product code HWC, and subsequent codes MBI and MAI, regulated under 21 CFR 888.3040 and 21 CFR 888.3030.

The proposed **TransTend Anchors** are suture anchors offered in three different

Device Description

materials, namely Biocryl Rapide, Titanium or Peek. The anchor comes preloaded on a disposable inserter assembly and is intended for fixation of size #2 suture to bone. The suture option is provided without needles. The TransTend Anchors are provided as size 3.4 mm in Biocryl Rapide, 3.4mm in Peek and 2.9 mm in Titanium. Each TransTend Anchor is provided sterile and is for single patient use only. The TranTend anchors will also be offered in a convenience kit and be packaged with a cannula assembly along with one or two TransTend Anchor(s).

Technologies characteristics including material for design, and packaging are the same as the predicates cleared devices.

Indications for Use

The TransTend Anchor is indicated for use in soft tissue to bone fixation in association with post-operative immobilization as follows:

	Indication	BR	PEEK	Titanium
Shoulder	Rotator Cuff	X	X	X
	Partial Thickness Rotator Cuff	X	X	X
	Biceps Tenodesis		X	X
	Acromio-Clavicular Separation		X	X
	Deltoid Repair		X	X
Foot/Ankle	Lateral Stabilization		X	X
	Medial Stabilization		X	X
	Mid-foot Reconstruction		X	X
	Hallux Valgus Repair		X	X
	Metatarsal Ligament/Tendon Repairs		X	X
Knee	Medial Collateral Ligament Repair		X	X
	Lateral Collateral Ligament Repair		X	X
	Posterior Oblique Ligament Repair		X	X
	Iliotibial Band Tenodesis		X	X
Elbow	Lateral Epicondylitis Repair		X	X
Wrist	Scapholunate Ligament Reconstruction		X	X
Hip	Capsular Repair		X	X
	Acetabular Labral Repair		X	X

Non clinical Testing

Verification activities were performed on the implant or its predicates. Testing includes pull out testing, insertion torque testing, sterilization and biocompatibility.

Safety and Performance

Results of performance and safety testing have demonstrated that the proposed devices are suitable for their intended use.

Based on the indications for use, technological characteristics, and comparison to the predicate devices, the proposed TransTend Anchors Anchor (s) have shown to be substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DePuy Mitek, Inc.
% Ms. Kristine Christo
Regulatory Affairs Project Manager
325 Paramount Drive
Raynham, Massachusetts 02767

JAN - 7 2011

Re: K102298
Trade/Device Name: TransTend (BR, Ti, Peek) Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, MAI
Dated: December 30, 2010
Received: January 03, 2011

Dear Ms. Christo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102298

Indications for Use

510(k) Number (if known): K102298

JAN - 7 2011

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	Iliotibial Band Tenodesis		X	X
Elbow	Lateral Epicondylitis Repair		X	X
Wrist	Scapholunate Ligament Reconstruction		X	X
Hip	Capsular Repair		X	X
	Acetabular Labral Repair		X	X

Prescription Use ____x____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKeown

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102298